REMARKS

Claims 21-23 are pending in this continuation application. No claims have been cancelled. No claims have been added. Claim 21 has been amended.

Claims 21-23 have been rejected under 35 U.S.C § 112, first paragraph, as being non-enabled by the specification. It is the Examiner's view that the specification does not enable a person skilled in the art to determine the subjects for whom oral contraceptives are indicated at a higher than normal incidence. The Examiner argues that the lack of guidance from the specification as to actual identification of these subjects makes practicing the invention unpredictable in terms of treating or preventing cervical dysplasia or cervical carcinoma.

Claim 21 has been amended, as set forth above, to make it clear that the subject population includes all women for whom oral contraceptives are indicated, since all of the members in this group are subject to an increased incidence of cervical dysplasia and cervical carcinoma due to folic acid deficiency. Thus, it should be understood that the subject group does not include those women for whom oral contraception is indicated at a higher than normal incidence but, as noted above, all women who are using oral contraceptives.

It is well documented in the art that women using oral contraceptives are subject to a number of risk factors associated with insufficient folic acid levels. As stated in the public health service recommendation cited in the specification at page 3, lines 9-13, all women who can become pregnant should consume 400 μg/day of folic acid to reduce the risk of birth defects (MMWR Morb Mortal Wkly Rep 1992; 41 (RR-14) : 1-7). In addition to the risk of birth defects resulting from insufficient folic acid levels, enhanced effects of risk factors for cervical dysplasia have been linked to decreased folic acid levels. In particular, locally diminished stores of folic acid in cervical tissue may be a result of oral contraceptive use. Studies have shown that administering folic acid can reduce the onset of cervical dysplasia. Sub-optimal body stores of folic acid may also amplify oncogenic risk. (Specification at page 4, lines 3-28). The risk factors associated with insufficient folic acid levels are further enhanced for women taking oral contraceptives, since multiple studies

have shown that women using oral contraceptives exhibit decreased folic acid levels relative to negative controls. (Specification at page 3, lines 19-25).

In view of the amendments to claim 1 clarifying the subject class, and further in view of the fact that the art recognizes maintaining sufficient folic acid levels reduces the risk factors for cervical dysplasia and cervical carcinoma associated with low folic acid levels, applicants believe that the Examiner withdraw the rejection of claims 21-23 under 35 U.S.C § 112, first paragraph.

Claims 21-23 have been rejected under 35 U.S.C § 103(a) over Wood et al. in view of Jackson '011). Applicants request that this rejection be withdrawn since these references do not teach or even suggest the claimed method. Wood merely restates what is already known in the art, i.e., the use of oral contraceptives can interfere with folic acid absorption and/or metabolism of folic acid. (See also, the instant specification at page 3, lines 18-25). Jackson '011 reiterates what is known in the art, as also set forth in the instant specification and discussed above, that women with decreased levels of folic acid are subject to increased risks for conditions such as cervical dysplasia and cervical cancer.

What the combination of these references neither teaches nor suggests is a method for administering folic acid wherein folic acid is administered in combination with an oral contraceptive as a single pharmaceutical composition. Such a method insures that as a woman regularly takes her oral contraceptive she automatically is administered the required amount of folic acid, thus eliminating the risk of cervical dysplasia and cervical carcinoma associated with insufficient folic acid levels.

Nowhere is this taught or suggested by the combination of Wood and Jackson. In fact, if these references were combined as suggested by the Examiner all they would teach is the administration of a dietary supplement combining vitamins, minerals and folic acid to address the risk factors associated with low folic acid levels. Only through applicants' own teachings could one skilled in the art be led to the claimed method, wherein folic acid is administered in combination with an oral contraceptive to insure that women using oral contraceptives maintain regular and sufficient folic acid supplementation. Such hindsight reconstruction of the prior art using applicants' own teachings is clearly impermissible. Accordingly, applicants request that the rejection issued under § 103(a) be withdrawn.

In view of the foregoing, applicants believe that claims 21-23 are in condition for allowance and a Notice of Allowance directed to these claims is requested at the earliest possible date.

Applicants hereby petition for a two-month extension of time in order to respond to the outstanding Office Action. Please charge the fee of $410.00 required under 27 C.F.R. § 1.17 (a)(2), and any additional fees that may be required to Deposit Account No. 10-0750/ORT-1316/JSK.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

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